Senate

General Assembly

File No. 236

January Session, 2007

Senate Bill No. 74

Senate, April 2, 2007

The Committee on Insurance and Real Estate reported through SEN. CRISCO of the 17th Dist., Chairperson of the Committee on the part of the Senate, that the bill ought to pass.

AN ACT CONCERNING OVERSIGHT OF PHARMACY BENEFIT MANAGEMENT PLANS.

Be it enacted by the Senate and House of Representatives in General Assembly convened:

Section 1. (NEW) (*Effective October 1, 2007*) As used in sections 1 to 10, inclusive, of this act:

(1) "Commission of Pharmacy" or "commission" means the Commission of Pharmacy appointed under section 20-572 of the general statutes;

(2) "Commissioner" means the Insurance Commissioner;

(3) "Cosmetic" means cosmetic, as defined in section 21a-92 of the general statutes;

(4) "Department" means the Insurance Department;

(5) "Device" means device, as defined in section 21a-92 of the general statutes;

(6) "Drug" means drug, as defined in section 21a-92 of the general statutes;

(7) "Enrollee" means a person eligible to receive benefits under a health benefit plan;

(8) "Equivalent drug product" means a drug product which has the same established name, active ingredient, strength or concentration, dosage form, and route of administration and which is formulated to contain the same amount of active ingredient in the same dosage form and to meet the same compendial or other applicable standards, such as strength, quality, purity and identity, but which may differ in characteristics such as shape, scoring, configuration, packaging, expiration time or date, and excipients, including, but not limited to, colors, flavors and preservatives;

(9) "Manufacturer" means a person, whether within or outside of this state, who produces, prepares, cultivates, grows, propagates, compounds, converts or processes, directly or indirectly, by extraction from substances of natural origin or by means of chemical synthesis or by a combination of extraction and chemical synthesis, or who packages, replicates, labels or relabels a container, under such manufacturer's own or any other trademark or label, any drug, device or cosmetic for the purpose of selling such items;

(10) "Insolvent" or "insolvency" means a financial situation in which, based upon the financial information required pursuant to sections 1 to 10, inclusive, of this act for the preparation of the pharmacy benefits manager's annual statement, the assets of the pharmacy benefits manager are less than the sum of the manager's liabilities and requires reserves;

(11) "Person" means person, as defined in section 38a-1 of the general statutes;

(12) "Pharmacist services" includes (A) drug therapy and other patient care services provided by a licensed pharmacist intended to

achieve outcomes related to the cure or prevention of a disease, elimination or reduction of a patient's symptoms, and (B) education or intervention by a licensed pharmacist intended to arrest or slow a disease process;

(13) "Pharmacist" means an individual licensed to practice pharmacy under section 20-590, 20-591, 20-592 or 20-593 of the general statutes, and who is thereby recognized as a health care provider by the state of Connecticut;

(14) "Pharmacy" means a place of business where drugs may be sold at retail and for which a pharmacy license has been issued to an applicant pursuant to section 20-594 of the general statutes;

(15) "Pharmacy benefits manager" or "manager" means any person that administers the prescription drug, prescription device, pharmacist services or prescription drug and device and pharmacist services portion of a health benefit plan on behalf of plan sponsors such as self-insured employers, insurance companies, labor unions and health care centers;

(16) "Pharmacy benefit management plan" or "plan" means an arrangement for the delivery of prescription services or pharmacist services in which a pharmacy benefits manager undertakes to provide, arrange for, pay for or reimburse any of the costs of prescription services for an enrollee on a prepaid or insured basis which (A) contains one or more incentive arrangements intended to influence the cost or level of prescription services between the plan sponsor and one or more pharmacies with respect to the delivery of prescription services, and (B) requires or creates benefit payment differential incentives for enrollees under contract with the pharmacy benefits manager. "Pharmacy benefit management plan" or "plan" does not include an employee welfare benefit plan unless it is administered through a pharmacy benefits manager; and

(17) "Wholesaler" or "distributor" means a person, whether within or outside of this state, who supplies drugs, devices or cosmetics

prepared, produced or packaged by manufacturers, to other wholesalers, manufacturers, distributors, hospitals, prescribing practitioners, as defined in section 20-571 of the general statutes, pharmacies, federal, state or municipal agencies or clinics. "Wholesaler" or "distributor" does not include: (A) A retail pharmacy or a pharmacy within a licensed hospital which supplies to another such pharmacy a quantity of a noncontrolled drug or a schedule III, IV or V controlled substance ordinarily stocked by such pharmacies to provide for the immediate needs of a patient pursuant to a prescription or medication order of an authorized practitioner, (B) a pharmacy within a hospital which supplies drugs to another hospital or an authorized practitioner for research purposes, or (C) a retail pharmacy which supplies a limited quantity of a noncontrolled drug or of a schedule II, III, IV or V controlled substance for emergency stock to a practitioner who is a medical director of a chronic and convalescent nursing home, or a rest home with nursing supervision or of a state correctional institution.

Sec. 2. (NEW) (*Effective October 1, 2007*) (a) Each pharmacy benefits manager that provides a pharmacy benefit management plan to a resident of this state shall obtain a license from the Insurance Department and shall file an annual statement with the Insurance Commissioner on such form as the commissioner may prescribe. The annual statement shall include: (1) A financial statement for the pharmacy benefits manager's organization, including its balance sheet and income statement which shall include all identified sources of revenue for the preceding calendar year; (2) the number of individuals enrolled during the year, the number of enrollees as of the end of the year and the number of enrollments terminated during the year; (3) any other information related to the operations of the pharmacy benefits manager required by the commissioner; and (4) a copy of a certified annual audit performed by an independent certified public accountant for the most recent year.

(b) Such pharmacy benefits manager shall (1) pay all fees, taxes and charges required by law; (2) maintain the minimum capital and

surplus required by the commissioner; (3) file any financial statement or report, certificate or other document that the commissioner deems necessary to obtain a full and accurate knowledge of the manager's affairs and financial condition; (4) maintain solvency; (5) maintain a financial condition, method of operation and manner of doing business sufficient to satisfy the commissioner that the manager can meet its obligations to all enrollees; (6) comply with all requirements of law; and (7) obtain a certificate of pharmacy practice from the Commission of Pharmacy.

(c) A nonrefundable application fee required in section 38a-11 of the general statutes, as amended by this act, shall accompany each application for a pharmacy benefits manager license submitted to the commissioner. The commissioner shall use the amount of such fees solely for the purpose of regulating pharmacy benefits managers.

(d) Each pharmacy benefits manager that offers a pharmacy benefit management plan shall obtain and renew its license as a pharmacy benefits manager. The commissioner may refuse to reissue a license or may place restrictions on the license of any pharmacy benefits managers if the commissioner finds the manager lacks required capital or surplus or if the commissioner finds that the manager has not satisfied the requirements of this section, except that prior to refusing to reissue a license, the commissioner shall provide the manager with ten days written notice and shall give the manager an opportunity to be heard at an informal hearing held by the commissioner or a designee. The manager may waive the right to such notice and hearing.

Sec. 3. (NEW) (*Effective October 1, 2007*) (a) Each pharmacy benefits manager that offers a pharmacy benefit management plan in this state shall obtain a certificate of pharmacy practice from the Commission of Pharmacy and shall (1) provide proof to the commission that the pharmacy benefits manager is operating in accordance with its basic organizational document; (2) pay all applicable fees; (3) maintain its license to operate as a pharmacy benefits manager in this state; (4) pay

any certificate and license renewal fees to the Department of Consumer Protection or the commission, as the case may be; (5) maintain its license from the Insurance Department pursuant to section 2 of this act; (6) pay pharmacies or pharmacists for pharmacists' services a ten per cent rebate for each drug or device dispensed through the plan to ensure proper education and safe prescription practices for the patient; (7) pay pharmacies and pharmacists a reasonable dispensing fee as determined by an independent cost of dispensing survey to ensure safe prescription practices; (8) pay pharmacies' transmittal costs; and (9) reimburse to the pharmacy at a rate of fifty per cent any funds generated from the selling of aggregate patient information whether specific or nonspecific.

(b) The Commissioner of Consumer Protection and the commission shall use the amount of any fee collected from a pharmacy benefit manager solely for the purpose of regulating pharmacy benefits managers.

Sec. 4. (NEW) (*Effective October 1, 2007*) Each pharmacy benefits manager that contracts with an approved pharmacy or pharmacist to provide services through a pharmacy benefit management plan for enrollees in this state shall file such contract with the Commission of Pharmacy at least thirty days before the execution of the contract. The contract shall be deemed approved unless disapproved by the commission not later than thirty days after the contract is filed. The commission shall adopt regulations, in accordance with chapter 54 of the general statutes, to develop formal criteria for the approval and disapproval of pharmacy benefits manager contracts.

Sec. 5. (NEW) (*Effective October 1, 2007*) Except as otherwise required by subdivision (6), (8) or (9) of section 3 of this act, no person may (1) pay, allow or give, or offer to pay, allow or give, directly or indirectly, as an inducement to any contract, rebate, special favor or other benefits, for switching to an equivalent or therapeutic drug product, unless the contract is filed and approved by the Commission of Pharmacy at least thirty days before execution of the contract; or (2)

receive or accept any rebate or any special favor or advantage of any valuable consideration or inducement not specified in the contract.

Sec. 6. (NEW) (*Effective October 1, 2007*) (a) No pharmacy benefits manager or its representative may cause or knowingly permit the use of (1) any advertising or solicitation that is untrue or misleading, or (2) any form of evidence of coverage that is deceptive.

(b) No pharmacy benefits manager that is not licensed as an insurer may use in its name, contracts or literature (1) the word "insurance", "casualty", "surety" or "mutual", or (2) any other words descriptive of insurance, casualty or surety business or deceptively similar to the name or description of any insurance or fidelity and surety insurer.

(c) No pharmacy benefits manager may discriminate on the basis of race, creed, color, gender or religion in the selection of pharmacies for participation in a plan operated by the manager.

(d) No pharmacy benefits manager may unreasonably discriminate against a pharmacy or pharmacist when contracting for pharmacy or pharmacist services.

(e) No pharmacy or pharmaceutical manufacturer may own a pharmacy benefits manager.

(f) No pharmacy benefits manager may discriminate when contracting with pharmacies on the basis of copayments or days of supply.

(g) No pharmacy benefits manager may discriminate when advertising which pharmacies are participating pharmacies. This list shall be complete and all inclusive.

Sec. 7. (NEW) (*Effective October 1, 2007*) Each pharmacy benefits manager shall provide the following information to enrollees in its plans at the time of enrollment or at the time the contract is issued, and shall make available upon request or at least annually:

(1) A list of the names and locations of all affiliated providers;

(2) A description of the service area or areas within which the pharmacy benefits manager provides prescription services;

(3) A description of the method of resolving complaints of covered persons, including a description of any arbitration procedure if complaints may be resolved through a specified arbitration agreement;

(4) Notice that the pharmacy benefits manager is subject to regulation by the Insurance Department; and

(5) A prominent notice included within the evidence of coverage which provides the following: "If you have any questions regarding an appeal or grievance concerning the pharmacist services that you have been provided which have not been satisfactorily addressed by your plan, you may contact the Insurance Department". Such notice shall provide the toll-free telephone number, mailing address and electronic mail address of the Insurance Department.

Sec. 8. (NEW) (*Effective October 1, 2007*) (a) The Insurance Department shall develop formal investigation and compliance procedures with respect to complaints by plan sponsors, pharmacists or enrollees concerning the failure of a pharmacy benefits manager to comply with the provisions of sections 1 to 7, inclusive, of this act. If the department has reason to believe that there is a violation of sections 1 to 7, inclusive, of this act, the department shall serve upon the manager a statement of the charges and a notice of a hearing to be held at a time and place set forth in the notice, which shall not be less than thirty days after the notice is served. The notice shall require the pharmacy benefits manager to show cause why an order should not be issued directing the manager to cease and desist from the violation. At such hearing, the pharmacy benefits manager shall have the opportunity to be heard and to show cause why an order should not be issued requiring the pharmacy benefits manager to cease and desist from the violation.

(b) The department, with the advice of the Commission of Pharmacy, may make an examination concerning the quality of services of any pharmacy benefits manager and providers with whom the pharmacy benefits manager has contracts, agreements or other arrangements pursuant to its pharmacy benefit management plan. Such examination may be made as often as the department deems necessary, or at the request of the commission. The pharmacy benefits manager being examined shall pay the cost of the examination.

Sec. 9. (NEW) (*Effective October 1, 2007*) An enrollee in a pharmacy benefit management plan shall have the right to privacy and confidentiality in pharmacy services, except that the enrollee or the enrollee's guardian may expressly waive such right in writing.

Sec. 10. (NEW) (*Effective October 1, 2007*) (a) If a pharmacy benefits manager becomes insolvent or ceases to operate in this state in any assessable year or any year during which licensure is required, the manager shall remain liable for the payment of any assessment for any period in which it operated as a pharmacy benefits manager in this state.

(b) In the event of an insolvency of a pharmacy benefits manager, the Insurance Commissioner may, after notice and a hearing, levy an assessment on pharmacy benefits managers licensed in this state. The Insurance Commissioner shall use the amount of any assessment collected pursuant to this section solely for the benefit of enrollees of the insolvent pharmacy benefits manager.

Sec. 11. Subsection (a) of section 38a-11 of the general statutes is repealed and the following is substituted in lieu thereof (*Effective October 1, 2007*):

(a) The commissioner shall demand and receive the following fees: (1) For the annual fee for each license issued to a domestic insurance company, one hundred dollars; (2) for receiving and filing annual reports of domestic insurance companies, twenty-five dollars; (3) for filing all documents prerequisite to the issuance of a license to an

insurance company, one hundred seventy-five dollars, except that the fee for such filings by any health care center, as defined in section 38a-175, shall be one thousand one hundred dollars; (4) for filing any additional paper required by law, fifteen dollars; (5) for each certificate of valuation, organization, reciprocity or compliance, twenty dollars; (6) for each certified copy of a license to a company, twenty dollars; (7) for each certified copy of a report or certificate of condition of a company to be filed in any other state, twenty dollars; (8) for amending a certificate of authority, one hundred dollars; (9) for each license issued to a rating organization, one hundred dollars. In addition, insurance companies shall pay any fees imposed under section 12-211; (10) a filing fee of twenty-five dollars for each initial application for a license made pursuant to section 38a-769; (11) with respect to insurance agents' appointments: (A) A filing fee of twenty-five dollars for each request for any agent appointment, except that no filing fee shall be payable for a request for agent appointment by an insurance company domiciled in a state or foreign country which does not require any filing fee for a request for agent appointment for a Connecticut insurance company; (B) a fee of forty dollars for each appointment issued to an agent of a domestic insurance company or for each appointment continued; and (C) a fee of twenty dollars for each appointment issued to an agent of any other insurance company or for each appointment continued, except that no fee shall be payable for an appointment issued to an agent of an insurance company domiciled in a state or foreign country which does not require any fee for an appointment issued to an agent of a Connecticut insurance company; (12) with respect to insurance producers: (A) An examination fee of seven dollars for each examination taken, except when a testing service is used, the testing service shall pay a fee of seven dollars to the commissioner for each examination taken by an applicant; (B) a fee of forty dollars for each license issued; (C) a fee of forty dollars per year, or any portion thereof, for each license renewed; and (D) a fee of forty dollars for any license renewed under the transitional process established in section 38a-784; (13) with respect to public adjusters: (A) An examination fee of seven dollars for each

examination taken, except when a testing service is used, the testing service shall pay a fee of seven dollars to the commissioner for each examination taken by an applicant; and (B) a fee of one hundred twenty-five dollars for each license issued or renewed; (14) with respect to casualty adjusters: (A) An examination fee of ten dollars for each examination taken, except when a testing service is used, the testing service shall pay a fee of ten dollars to the commissioner for each examination taken by an applicant; (B) a fee of forty dollars for each license issued or renewed; and (C) the expense of any examination administered outside the state shall be the responsibility of the entity making the request and such entity shall pay to the commissioner one hundred dollars for such examination and the actual traveling expenses of the examination administrator to administer such examination; (15) with respect to motor vehicle physical damage appraisers: (A) An examination fee of forty dollars for each examination taken, except when a testing service is used, the testing service shall pay a fee of forty dollars to the commissioner for each examination taken by an applicant; (B) a fee of forty dollars for each license issued or renewed; and (C) the expense of any examination administered outside the state shall be the responsibility of the entity making the request and such entity shall pay to the commissioner one hundred dollars for such examination and the actual traveling expenses of the examination administrator to administer such examination; (16) with respect to certified insurance consultants: (A) An examination fee of thirteen dollars for each examination taken, except when a testing service is used, the testing service shall pay a fee of thirteen dollars to the commissioner for each examination taken by an applicant; (B) a fee of two hundred dollars for each license issued; and (C) a fee of one hundred twenty-five dollars for each license renewed; (17) with respect to surplus lines brokers: (A) An examination fee of ten dollars for each examination taken, except when a testing service is used, the testing service shall pay a fee of ten dollars to the commissioner for each examination taken by an applicant; and (B) a fee of five hundred dollars for each license issued or renewed; (18) with respect to fraternal agents, a fee of forty dollars

for each license issued or renewed; (19) a fee of thirteen dollars for each license certificate requested, whether or not a license has been issued; (20) with respect to domestic and foreign benefit societies shall pay: (A) For service of process, twenty-five dollars for each person or insurer to be served; (B) for filing a certified copy of its charter or articles of association, five dollars; (C) for filing the annual report, ten dollars; and (D) for filing any additional paper required by law, three dollars; (21) with respect to foreign benefit societies: (A) For each certificate of organization or compliance, four dollars; (B) for each certified copy of permit, two dollars; and (C) for each copy of a report or certificate of condition of a society to be filed in any other state, four dollars; (22) with respect to reinsurance intermediaries: A fee of five hundred dollars for each license issued or renewed; (23) with respect to viatical settlement providers: (A) A filing fee of thirteen dollars for each initial application for a license made pursuant to section 38a-465a; and (B) a fee of twenty dollars for each license issued or renewed; (24) with respect to viatical settlement brokers: (A) A filing fee of thirteen dollars for each initial application for a license made pursuant to section 38a-465a; and (B) a fee of twenty dollars for each license issued or renewed; (25) with respect to viatical settlement investment agents: (A) A filing fee of thirteen dollars for each initial application for a license made pursuant to section 38a-465a; and (B) a fee of twenty dollars for each license issued or renewed; (26) with respect to preferred provider networks, a fee of two thousand five hundred dollars for each license issued or renewed; (27) with respect to rental companies, as defined in section 38a-799, a fee of forty dollars for each permit issued or renewed; (28) with respect to medical discount plan organizations licensed under section 38a-479rr, a fee of five hundred dollars for each license issued or renewed; (29) with respect to pharmacy benefits managers, an application fee of fifty dollars for each license issued or renewed; and **[**(29)**]** (30) with respect to each duplicate license issued a fee of twenty-five dollars for each license issued.

This act shall take effect as follows and shall amend the following sections:		
Section 1	*October 1, 2007*	New section
Sec. 2	*October 1, 2007*	New section
Sec. 3	*October 1, 2007*	New section
Sec. 4	*October 1, 2007*	New section
Sec. 5	*October 1, 2007*	New section
Sec. 6	*October 1, 2007*	New section
Sec. 7	*October 1, 2007*	New section
Sec. 8	*October 1, 2007*	New section
Sec. 9	*October 1, 2007*	New section
Sec. 10	*October 1, 2007*	New section
Sec. 11	*October 1, 2007*	38a-11(a)

INS *Joint Favorable*

The following fiscal impact statement and bill analysis are prepared for the benefit of members of the General Assembly, solely for the purpose of information, summarization, and explanation, and do not represent the intent of the General Assembly or either chamber thereof for any purpose:

OFA Fiscal Note

State Impact:

Agency Affected	Fund-Effect	FY 08 $	FY 09 $
Insurance Dept.	IF - Cost	250,027	253,616
Insurance Dept.	GF - Revenue Gain	Minimal	Minimal

Note: IF=Insurance Fund; GF=General Fund

Municipal Impact: None

Explanation

This bill would result in a cost of approximately $250,000 related to the requirement that pharmacy benefit managers (PBM's) be licensed with the Insurance Department. Detail appears below:

Item	FY 08	FY 09
Examiner	63,804	65,718
Attorney	60,807	62,631
Consultants	36,000	36,000
Court Reporters (hearings) & supplies	12,000	12,000
Start-up computer equipment	2,400	0
Fringe Benefits	75,016	77,266
Total	**250,027**	**253,616**

The additional examiner would establish licensure procedures, including associated workload of correspondence, review, and other administrative duties, as well as work with the outside consultant(s). The outside consultants would perform the annual financial review of annual reports submitted to the Insurance Department from the PBM's, and the attorney would develop formal investigation and compliance procedures with respect to complaints from plan sponsors and enrollees pertaining to the failure of the pharmacy manager to comply with provisions in the bill.

This bill could also yield minimal revenue as a result of PBM's new licensure requirement within the Insurance Department.

The Out Years

The annualized ongoing fiscal impact identified above would continue into the future subject to inflation and subject to the number of PBM's that seek licensure with the state.

OLR Bill Analysis

SB 74

AN ACT CONCERNING OVERSIGHT OF PHARMACY BENEFIT MANAGEMENT PLANS.

SUMMARY:

This bill requires pharmacy benefit managers (PBMs) to obtain a PBM license from the Insurance Department and a certificate of pharmacy practice from the Commission of Pharmacy. It requires the commissioners of the departments of Insurance and Consumer Protection (DCP) and the Pharmacy Commission to regulate PBMs.

The bill requires PBMs to comply with specific requirements concerning (1) pharmacy plans and related enrollee materials, (2) rebates and other incentives, (3) selecting and contracting with pharmacies, (4) advertising, and (5) insolvency assessments. It requires the insurance commissioner to establish a PBM complaint investigation process. It also establishes a right to privacy and confidentiality in pharmacy services for people enrolled in a PBM's pharmacy plan. The right may be waived.

The bill prohibits a pharmacy or pharmaceutical manufacturers from owning a PBM. (This affects future and existing contractual arrangements between plan sponsors and PBMs.)

EFFECTIVE DATE: October 1, 2007

PHARMACY BENEFIT MANAGER

Under the bill, "pharmacy benefits manager"(PBM) means a person that administers the prescription drug, prescription device, or pharmacist services portion of a health benefit plan on behalf of plan sponsors (e.g., self-insured employers, insurers, labor unions, or

HMOs).

Insurance Department License Requirements (§ 2)

The bill requires a PBM that provides a pharmacy benefit management plan to a state resident to obtain a license from the Insurance Department and renew it as required. A "pharmacy benefit management plan" (pharmacy plan) is an arrangement for the delivery of pharmacy or pharmacist services in which a PBM provides, arranges for, pays for, or reimburses any of the prescription costs for an enrollee on a prepaid or insured basis.

The bill (1) contains one or more incentives to influence the cost or level of prescription services between the plan sponsor and one or more pharmacies and (2) requires or creates different levels of benefit payments for enrollees. It excludes any employee welfare benefit plan not administered through a PBM.

The bill requires the PBM to file a statement annually with the insurance commissioner (but does not specify a filing date). The filing must include:

1. a financial statement for the PBM's organization, including its balance sheet and income statement, identifying all revenue sources for the preceding calendar year (which assumes the PBM's fiscal year runs on a calendar year basis);

2. the number of people enrolled during the year, as of the end of the year, and terminated during the year;

3. any other information related to the PBM's operations the commissioner may require; and

4. a copy of a certified annual audit performed by an independent certified public accountant for the most recent year.

The bill requires the PBM to:

1. pay all fees, taxes, and charges required by law;

2. maintain the minimum capital and surplus the commissioner requires;

3. file any financial statement, report, certificate, or other document the commissioner needs to fully and accurately know the manager's affairs and financial condition;

4. maintain solvency;

5. maintain a financial condition, method of operation, and manner of doing business that satisfies the commissioner that the PBM can meet its obligations to all enrollees;

6. comply with all laws; and

7. obtain a certificate of pharmacy practice from the Commission of Pharmacy.

When applying for a license or a license renewal, the PBM must submit a nonrefundable $50 fee to the commissioner, who must use the fees to regulate PBMs. (The bill does not specify how often a license must be renewed, or alternatively, when a license expires.) The commissioner may refuse to renew a PBM's license or may place restrictions on it if the PBM lacks the required capital or surplus or has not satisfied the licensing requirements. Before refusing to renew a license, the commissioner must give the PBM 10 days written notice and an opportunity to be heard at an informal hearing the commissioner or a designee holds. The PBM may waive the right to such notice and hearing.

Certificate of Pharmacy Practice (§ 3)

The bill requires a PBM offering a pharmacy plan in the state to obtain a certificate of pharmacy practice from the Commission of Pharmacy (commission). (It does not set forth procedures for this.)

The bill requires the PBM to:

1. provide the commission proof that it is operating in accordance

with its basic organizational document;

2. pay all applicable fees (which are not specified);

3. maintain its license to operate as a PBM in this state;

4. pay any certificate and license renewal fees to the DCP or the commission, as the case may be, (but does not specify the fees or require a PBM to obtain a license from the DCP or commission);

5. maintain its Insurance Department license (presumably the same license as item three above);

6. pay pharmacies or pharmacists a 10% rebate for each drug or device dispensed through the pharmacy plan to ensure proper education and safe prescription practices for the patient;

7. pay pharmacies and pharmacists a reasonable dispensing fee based on an independent dispensing cost survey to ensure safe prescription practices (it does not indicate who is to perform the survey);

8. pay pharmacies' transmittal costs; and

9. reimburse the pharmacy 50% of any funds generated from selling aggregate patient information, whether specific or nonspecific. (It is unclear how aggregate data could be specific. The federal Health Insurance Portability and Accountability Act (HIPAA) confidentiality requirements may be implicated here.)

The DCP commissioner and the commission must use any fees collected from PBMs to regulate PBMs.

PBM Contracts with Pharmacists (§ 4)

The bill requires a PBM that contracts with a pharmacy or pharmacist to provide pharmacy services to pharmacy plan enrollees to file the contract with the commission at least 30 days before executing it. The contract is deemed approved unless the commission

disapproves it within 30 days from the filing date. The commission must adopt regulations to develop formal criteria for approving and disapproving PBM contracts. (While in theory the commission could adopt regulations, in practice, and as stated in other statutes, DCP usually adopts the regulations with the advice and assistance, consultation, or approval of the commission.)

Switching Prescription Drugs (§ 5)

Under the bill, no one may directly or indirectly pay, allow, or give, or offer to, as an inducement to any contract, a rebate, special favor, or other benefit for switching to an equivalent or therapeutic drug product, unless the commission approves the contract. Also, no one may receive or accept a rebate, special favor, or advantage of any valuable consideration or inducement not specified in the contract. But the PBM may still pay the 10% rebate, transmittal fees, and 50% of funds received for selling patient data funds, as required in § 3, above.

The bill defines "equivalent drug product" as a drug product that (1) has the same established name, active ingredient, strength or concentration, dosage form, and route of administration, and (2) is formulated to contain the same amount of active ingredient in the same dosage form to meet the same compendial or other applicable standards, such as strength, quality, purity, and identity. But it may differ in characteristics such as shape, scoring, configuration, packaging, expiration time or date, and excipients, including colors, flavors, and preservatives.

The definition appears to conflict with the Pharmacy Practices Act, which defines "therapeutically equivalent" as drug products approved under the federal Food, Drug and Cosmetics Act for interstate distribution and that provide essentially the same efficacy and toxicity when administered to a person in the same dosage regimen (CGS § 20-619(a)(3)). It is unclear if the bill conflicts with the Pharmacy Practices Act provision that permits a pharmacy to substitute a drug product when there will be a savings in cost passed on the customer, as long as the pharmacist discloses the amount of savings at the customer's

request (CGS § 20-619(e)).

Prohibitions (§ 6)

The bill prohibits PBMs from engaging in specified activities. A PBM or its representative may not cause or knowingly permit the use of any (1) untrue or misleading advertising or solicitation or (2) deceptive evidence of coverage form.

A PBM that is not licensed as an insurer may not use in its name, contracts, or literature (1) insurance, casualty, surety, or mutual or (2) any other words that are descriptive of insurance, casualty, or surety business or deceptively similar to any insurer's name or description.

A PBM may not discriminate on the basis of race, creed, color, gender, or religion in the selection of pharmacies for participation in a plan operated by the manager.

A PBM may not unreasonably discriminate against a pharmacy or pharmacist when contracting for pharmacy or pharmacist services. (The bill does not define "unreasonably discriminate.")

A pharmacy or pharmaceutical manufacturer (e.g., CVS, Merck, Eli Lilly) may not own a PBM.

A PBM may not discriminate when contracting with pharmacies on the basis of copayments or days of supply.

A PBM may not discriminate when advertising participating pharmacies. The list (apparently a list of participating pharmacies in the advertising material) must be complete and all inclusive.

Information to Enrollees (§ 7)

The bill requires a PBM to provide certain information to pharmacy plan enrollees (1) when they enroll or the contract is issued and (2) upon request or at least annually. The information includes:

1. the names and locations of all affiliated providers (presumably participating pharmacies and pharmacists);

2. the PBM service areas;

3. the complaint resolution process, including any arbitration procedure that may apply;

4. a notice that the Insurance Department regulates the PBM; and

5. a prominent notice in the evidence of coverage that reads: "If you have any questions regarding an appeal or grievance concerning the pharmacist services that you have been provided which have not been satisfactorily addressed by your plan, you may contact the Insurance Department." This notice must include the Insurance Department's toll-free telephone number, mailing address, and e-mail address.

Insurance Department Complaint Investigation (§ 8)

The bill requires the Insurance Department to develop formal investigation and compliance procedures for complaints that PBMs are not complying with the bill.

If the department has reason to believe a PBM is in violation, it must give it a statement of the charges and a hearing notice. The department must hold the hearing at a time and place stated in the notice at least 30 days after serving the notice. The notice must require the PBM to show cause why the department should not issue a cease and desist order to stop the violations. At the hearing, the PBM must have the opportunity to be heard and to show such cause. (This procedure appears to conflict with the Uniform Administrative Procedure Act by not including an appeal process, including appealing to superior court after exhausting administrative remedies.)

The department, with the commission's advice, may examine a PBM's quality of services and contracted providers as often as it deems necessary, or at the commission's request. The PBM must pay for the examination.

Right to Privacy and Confidentiality (§ 9)

The bill creates a pharmacy plan enrollee's right to privacy and confidentiality in pharmacy services. The enrollee or the enrollee's guardian may expressly waive the right in writing. (It is unclear if this is compatible with existing confidentiality requirements, including those in the Pharmacy Practices Act (CGS § 20-626), the dependency-producing drug laws (CGS § 21a-265), and federal HIPAA.)

Insolvency Assessment (§ 10)

In the event of a PBM's insolvency, the bill authorizes the insurance commissioner, after notice and hearing, to levy an assessment on PBMs licensed in the state. (Apparently the commissioner may assess PBMs as often as he or she deems necessary.) The commissioner must use the assessments collected solely for the benefit of the insolvent PBM's enrollees (presumably to pay outstanding pharmacy claims).

If a PBM becomes insolvent or ceases to operate in the state in any assessable year or any year for which licensure is required, the PBM remains liable for paying any assessment due for any time it operated as a PBM. (The bill does not define "assessable year.")

The bill defines "insolvent" as a financial situation in which, based on the financial information required to prepare the PBM's annual statement that must be filed with the commissioner, the PBM's assets are less than the sum of its liabilities and "requires reserves". (This should probably be "required" reserves.)

Wholesaler or Distributor (§ 1)

The bill defines "wholesaler or distributor," but does not use these terms.

COMMITTEE ACTION

Insurance and Real Estate Committee

Joint Favorable
Yea 13 Nay 6 (03/13/2007)